Remarks

Claims 1, 2, 4-27, 29, and 30 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 4, 5, and 23-26. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at pages 3 and 4 of the application. Accordingly, claims 1, 2, 4-27, 29, and 30 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the objection set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Claims 1-2, 4-27, 29, and 30 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With regard to the rejection of claims 1, 2, 4-22, and 23-25 the Office Action indicates at pages 2-4 that the claims are indefinite because there is no recitation of how the medication is to be taken. The applicants respectfully disagree. The skilled artisan, having read the application, would readily understand the metes and bounds of the claims. Specifically, the skilled clinician having read the subject application, would readily recognize the many different forms that a medication can be administered to a patient, wherein oral administration is merely one form of administration (see, for example, p. 11, lines 23-27; and p. 14, line 20 through p. 15, line 6). Further, as clearly recited in the claims and the subject specification, the focus of the claimed invention is to ascertain whether a patient has complied in taking any medication as prescribed. Depending on the type of medication prescribed, the skilled artisan would readily recognize how the medication is to be taken and as such, would understand the metes and bounds of the claims as they relate to assessing patient compliance. Accordingly, reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. §112, second paragraph is respectfully requested.

With regard to the rejection of claims 23-25 as indefinite, the applicants respectfully submit that the skilled artisan, having read the subject application, would readily understand how the odorous markers would be readily detected in exhaled breath. As described in detail in the

application, see pages 11-13, various forms of odorous markers can be utilized to assess patient compliance in taking a prescribed medication. Depending on the mode of administration, the odorous marker can be detected following enzymatic breakdown or breakdown in the gastrointestinal tract. In an effort to expedite prosecution, the applicants have amended claims 23-25 to clarify the specific markers that can be utilized in accordance with the subject invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph.

With regard to the rejection of claim 17 as indefinite, the applicants respectfully submit that claim 17 clearly and distinctly points out the subject matter regarded as the invention. However, in an effort to expedite prosecution, the applicants have amended claim 17 to clarify that the results obtained from the steps of claim 1 are transmitted to an interested individual. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

With regard to the rejection of claims 5, 25, 26, and 29, the applicants respectfully submit that the claims as currently presented are complete and do not omit any essential steps. As noted above, the focus of the subject invention is to ascertain whether a patient has complied in taking a medication as prescribed. To do so, the subject invention teaches providing to a patient a medication with an odorous marker and subsequently sampling and assessing the patient's breath to determine whether the odorous marker is present therein. Presence of the odorous marker in the patient's breath is an indicator of patient compliance in taking the medication. That being the case, the step of having the patient take the medication is clearly not an essential step necessary to practice the invention.

Further, with regard to the rejection of claims 5 and 26 for omitting an essential step, the applicants respectfully submit that there is no recitation in claim 5 regarding the determination of the concentration of the odorous marker. Rather, claim 26 recites the step of assessing odorous marker concentration in the patient's breath. In an effort to clarify the claimed subject matter, claim 5 has been amended to clarify that the unique fingerprint generated by the sensor is used to determine the presence of the odorous marker in the patient's breath. In addition, claim 26 has been amended to

clarify the steps of assessing the concentration of the odorous marker in the patient's breath following the step of determining patient compliance in taking a medication as prescribed. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. §112, second paragraph.

With regard to the rejection of claim 29, the applicants respectfully submit that claim 29 is definite with regard to how the medication is to be manufactured. The fact that claim language may not be precise does not automatically render the claim indefinite under 35 U.S.C. §112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packing Inc.*, 731 F.2d 818, 221 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. The applicants respectfully submit that it is well known to the skilled artisan what is involved in combining an odorous marker compound with a medication to be administered to a patient. Further, the subject specification at page 13, lines 14-19 provides detailed description regarding ways in which a medication with odorous marker can be manufactured. When the claims are read in light of the specification and the knowledge base of those skilled in the art, it is not necessary for the applicants to clarify how the odorous marker medication is to be is obtained. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claims 1, 2, 7-9, 12-21 and 23-27, 29, and 30 have been rejected under 35 U.S.C. §102(e) as being anticipated by Katzman (U.S. Patent No. 5,962,335). The subject application is directed to ascertaining patient compliance in taking a medication based on detecting in exhaled breath the presence or absence of an odorous marker associated with the medication. The applicants respectfully traverse the grounds for this rejection because Katzman neither teaches nor suggests the subject invention as currently presented.

Katzman merely describes a method for monitoring patient metabolism of a isotopically-labeled drug by assessing whether the isotope is present in a patient's breath. Nowhere does Katzman ever describe how or why one would assess a patient's breath for odorous compounds. In sharp contrast to Katzman, the instant invention is directed to methods for determining patient compliance in taking medication, as opposed to patient metabolism. The step of assessing for and

determining the presence or absence of an odorous marker in the patient's breath is recited in all of the claims, and such step is used to determine patient compliance.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The applicants respectfully submit that Katzman *et al.* does not disclose any methods for assessing odorous compounds in a patient's breath to monitor patient compliance in taking a medication. Because Katzman *et al.* does not disclose or even suggest methods for assessing patient breath for odorous markers, the applicants' claims cannot be said to be anticipated by Katman *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §102(e).

Claims 1, 2, 6, and 9-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Forester (U.S. Patent No. 4,762,719). The applicants respectfully traverse the grounds for this rejection because Forester does not teach or disclose the claimed invention, that being methods for assessing odorous compounds in exhaled breath to determine patient compliance in taking a medication.

Forester merely teaches a cough drop that includes ingredients that vaporize into the oral and nasal cavities to treat coughing. Forester does not teach or suggest, in any fashion, methods for monitoring patient compliance in taking a prescribed medication. Further, Forester neither teaches nor suggests the step of sampling exhaled breath from a patient and analyzing the sample to ascertain patient compliance in taking a medication, as recited in the claims. Finally, there is no teaching or

suggestion in Forester regarding medications with odorous markers that are detectable in gaseous exhaled breath, as recited in the claims. Rather, Forester merely teaches a cough product for treating coughs. Because Forester does not disclose each and every element of the claimed invention, Forester cannot anticipate. Accordingly, reconsideration of this rejection is respectfully requested.

Claims 4 and 5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Forester in view of Payne (WO 98/39470) and in view of Kell (U.S. Patent No. 5,652,146). The applicants respectfully traverse these grounds for rejection and hereby incorporate by reference the comments asserted above regarding Forester.

As noted above, nothing in Forester would have led the skilled artisan to the advantageous methods currently claimed by applicants. Payne merely discloses the diagnosis of a medical condition, such as an infection or disease, using known sensors. Kell discloses the administration of medication and a marker, methadone, which is to be measured in a patient's urine sample to assess patient compliance in taking the medication. As the skilled artisan would readily acknowledge, the marker disclosed by Kell must be metabolized and excreted in urine and is not detectable in exhaled breath. There is no teaching or suggestion whatsoever by either Forester, Payne, or Kell regarding the steps of assessing patient exhaled breath for the presence of an odorous marker for use in determining patient compliance in taking a medication. Specifically, none of the references describe the steps of providing to a patient a medication and an odorous marker detectable in gaseous exhaled breath; using a sensor to detect the presence and or absence of the odorous marker in a sample of exhaled breath taken from the patient; and based on the presence or absence of the odorous marker in the sample, determining whether the patient was compliant in taking the medication.

The Office Action suggests that it would have been obvious to combine the cough medication of Forester with the methods of clinical diagnosis as taught by Payne and Kell's use of markers that must be metabolized to be detectable in urine to provide the subject invention for assessing patient compliance via analysis of exhaled breath. The applicants respectfully disagree.

A *prima facie* finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. The courts have consistently held that when a §103 rejection is based upon a modification of a reference that destroys the intent, purpose, or function of the

invention disclosed in the reference, such a proposed modification is not proper and the *prima facie* case of obviousness cannot properly be made. The skilled artisan, having knowledge of Forester, Payne, and Kell would not have any motivation for combining the three technologies to arrive at the claimed invention. Because Forester is directed to a medication to treat coughing, Payne is directed to diagnosing a medical condition, and Kell is directed to providing markers for urine analysis, the skilled artisan would not have considered combining the references to derive a method for ascertaining patient compliance in taking a prescribed medication. Nowhere in any of the references is there a teaching or suggestion regarding the steps of: provide to a patient a medication-odorous marker combination, and assessing the patient's breath for the presence or absence of the odorous marker, which are recited in the claims. Further, if the cough medication of Forester were combined with the method of clinical diagnosis of Payne, the intended purpose of Forester's invention, that being to provide a cough drop for treating coughing, would be destroyed if the vapors from the cough drop was used to diagnose a clinical condition (which conceivably was already diagnosed since the cough medication is given to treat the condition of coughing), as suggested in the Office Action.

Here, it is only the applicants' disclosure that provides a teaching for monitoring patient compliance in taking a medication via the detection of odorous markers in exhaled breath, and applicants' disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield the applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127

(Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art . . . ." *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). As noted above, the skilled artisan would not have found reason to combine Forester, Payne, and Kell to make the claimed invention because the combination of the teachings would destroy the intent, purpose, and function of the invention disclosed in Forester. Thus, the combination of the references as provided in the Office Action that forms the basis of this rejection is not proper and the *prima facie* case of obviousness cannot be made. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 22 has been rejected under 35 U.S.C. §103(a) as being obviours over Forester in view of Payne and in view of Ueda. The applicants respectfully traverse, and hereby incorporate by reference the comments asserted above in regard to Forester and Payne.

The shortcomings of Forester and Payne are not cured by Ueda. Ueda discloses a device for sampling and analyzing exhaled breath for components. Although Ueda suggests using its device for diagnosing a disease (see col. 14, lines 30-35), there is no teaching or suggestion by Ueda regarding the steps of providing a medication-odorous marker combination to a patient and of assessing the patient's exhaled breath for the presence or absence of the odorous marker that are recited in the claims. As noted above, the skilled artisan would not have found reason to combine Forester and Payne to make the claimed invention because the combination of the teachings would destroy the intent, purpose, and function of the invention disclosed in Forester. Ueda does not cure these shortcomings. Thus, the applicants respectfully submit that no case of *prima facie* obviousness has been set forth. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of claims under 35 U.S.C. §103.

Claim 22 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Katzman in view of Payne and in view of Ueda. The applicants respectfully traverse, and hereby incorporate by reference the comments asserted above in regard to Katzman, Payne, and Ueda. Katzman describes methods for monitoring patient metabolism using radiolabeled medications; Payne describes methods for clinical diagnosis; and Ueda describes a device for analyzing exhaled breath

components. None of the references describe or suggest methods for monitoring patient compliance in taking a medication. In fact, none of the references describe or even suggest the steps of providing to a patient a medication in combination with an odorous marker and assessing the patient's breath to determine the presence or absence of the odorous marker that are recited in the claims. Because the deficiencies of Katzman are not cured by either Payne or Ueda relied on in the office action, this obviousness rejection should be withdrawn. Reconsideration is respectfully requested.

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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